

EXHIBIT 14



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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED: 07/15/2011

Please find below and/or attached an Office communication concerning this application or proceeding.



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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

Date:

KING & SPALDING

1185 AVENUE OF THE AMERICAS

NEW YORK, NY 10036-4003

MAILED

JUL 15 2011

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011430

PATENT NO. : 7585311

ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).



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KNOBBE MARTENS OLSON & BEAR LLP
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(Patent Owner)

MAILED

JUL 15 2011

CENTRAL REEXAMINATION UNIT

KING & SPALDING
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-4003

(Third Party Requester)

In re Green et al.

Reexamination Proceeding

Control No.: 90/011,430

Filed: January 11, 2011

For: U.S. Patent No.: 7,585,311

: **DECISION**
: **ON PETITION**
: **UNDER 37 CFR 1.182**
:
:

This is a decision on the April 28, 2011 patent owner petition under 37 CFR 1.182 to enter, and to have the examiner consider, patent owner's information disclosure statement (IDS) filed after the termination of the prosecution in this reexamination proceeding.

The petition is before the Office of Patent Legal Administration for decision.

The petition is dismissed for the reasons set forth below.

Thus, the IDS filed on April 12, 2011 and again on April 28, 2011, has not been entered for consideration by the examiner.

BACKGROUND

1. On September 8, 2009, the Office issued U.S. Patent No. 5,585,311, to Green *et al.* (the '311 patent).
2. On January 11, 2011, a third party requester filed a request for *ex parte* reexamination of the '311 patent. The request was assigned reexamination proceeding control number 90/011,430 (the '11430 proceeding).
3. On February 16, 2011, the Office issued an order granting reexamination for the '11430 reexamination proceeding.
4. On February 24, 2011, patent owner filed a waiver of right to file a patent owner statement.
5. On March 28, 2011, the Office issued a Notice of Intent to Issue a Reexamination Certificate (NIRC) for the '11430 proceeding.

6. On April 1, 2011, the '11430 proceeding entered the printing cycle and designated 452 status.
7. On April 12, 2011, patent owner submitted an IDS without a petition.
8. On April 28, 2011, patent owner filed the instant petition accompanied by the same IDS filed on April 12, 2011, which patent owner requests the Office to consider.
9. The '11430 reexamination proceeding is in the final phase of the publication process for printing the reexamination certificate (*i.e.* it is in the printing cycle).

RELEVANT LAW AND PROCEDURE

35 U.S.C. 305 states (in pertinent part):

... All reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, will be conducted with **special dispatch** within the Office. [Emphasis added.]

37 CFR 1.97 states (in pertinent part):

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing of a first Office action on the merits; or
- (4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

37 C.F.R. 1.555(a) states (in pertinent part):

... Any information disclosure statement must be filed with the items listed in § 1.98(a) as applied to individuals associated with the patent owner in a reexamination proceeding, and should be filed within two months of the date of the order for reexamination, or as soon thereafter as possible. [Emphasis added]

MPEP 2256 states (in pertinent part):

.....Once the NIRC has been mailed, the reexamination proceeding must proceed to publication of the Reexamination Certificate as soon as possible. Thus, when the patent owner provides a submission of patents and printed publications, or other information described in 37 CFR 1.98(a), after the NIRC has been mailed, the submission must be accompanied by (A) a factual accounting providing a sufficient explanation of why the information submitted could not have been submitted earlier, and (B) an explanation of the relevance of the information submitted with respect to the claimed invention in the reexamination proceeding. This is provided via a petition under 37 CFR 1.182 (with petition fee) for entry and consideration of the information submitted after NIRC. The requirement in item (B) above is for the purpose of facilitating the Office's compliance with the statutory requirement for "special dispatch," when the requirement in item (A) above is satisfied to provide a basis for interrupting the proceeding after the NIRC.

Once the reexamination has entered the Reexamination Certificate publication process, pulling the proceeding from that process provides an even greater measure of delay. 37 CFR 1.313 states for an application (emphasis added):

"(c) Once the issue fee has been paid, the application will not be withdrawn from issue upon petition by the applicant for any reason except:

(1) Unpatentability of one or more claims, which petition must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;"

The publication process for an application occurs after the payment of the issue fee (there is no issue fee in reexamination), and thus 37 CFR 1.313(c) applies during the publication cycle for an application. Based on the statutory requirement for "special dispatch," the requirements for withdrawal of a reexamination proceeding from its publication cycle are at least as burdensome as those set forth in 37 CFR 1.313(b) and (c). **Accordingly, where a submission of patents and printed publications, or other information described in 37 CFR 1.98(a), is made while a proceeding is in its publication cycle, the patent owner must provide an unequivocal statement as to why the art submitted makes at least one claim unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable.** This is in addition to the above-discussed (A) a factual accounting providing a sufficient explanation of why the information submitted could not have been submitted earlier. The submission of patents and printed publications must be accompanied by a petition under 37 CFR 1.182 (with petition fee) for withdrawal of the reexamination proceeding from the publication process for entry and consideration of the information submitted by patent owner. A grantable petition must provide the requisite showing discussed in this paragraph. [Emphasis added]

MPEP 2280 states (in pertinent part):

... Such individuals are strongly encouraged to file information disclosure statements in accordance with 37 CFR 1.98, within two months of the date of the order to reexamine, or as soon thereafter as possible, in order to bring the patents or printed publications to the attention of the Office.

DECISION

There is no issue fee in reexamination, and the present reexamination proceeding has entered the final phase of the publication process (the "printing cycle"). In a reexamination proceeding, there is no withdrawal under 37 CFR 1.313 of the proceeding from the publication process for consideration of an Information Disclosure Statement (IDS), because 37 CFR 1.313(a) applies to applications, and not to reexamination proceedings. Accordingly, in this instance, the petition for withdrawal of the present proceeding from the publication process, for consideration of the accompanying IDS papers, has been filed under 37 CFR 1.182.

While there is no regulatory provision for withdrawal of a reexamination proceeding from the publication process for consideration of an IDS, the policy for withdrawal from the publication process, after the NIRC has been mailed but before the proceeding has actually entered the printing cycle, is explicitly set forth in MPEP 2256 as follows:

... Once the NIRC has been mailed, the reexamination proceeding must proceed to publication of the Reexamination Certificate as soon as possible. Thus, when the patent owner provides a submission of patents and printed publications, or other information described in 37 CFR 1.98(a), after the NIRC has been mailed, the submission must be accompanied by (A) **a factual accounting providing a sufficient explanation of why the information submitted could not have been submitted earlier, and (B) an explanation of the relevance of the information submitted with respect to the claimed invention in the reexamination proceeding.** This is provided via a petition under 37 CFR 1.182 (with petition fee) for entry and consideration of the information submitted after NIRC. The requirement in item (B) above is for the purpose of facilitating the Office's compliance with the statutory requirement for "special dispatch," when the requirement in item (A) above is satisfied to provide a basis for interrupting the proceeding after the NIRC.

The requirements of 37 CFR 1.313 for withdrawal of an application from the printing cycle (after the issue fee has been paid) have historically been applied, in an analogous manner, to requests for withdrawal of reexamination proceedings from the printing cycle. This policy is explicitly set forth in MPEP 2256 as follows:

... The publication process for an application occurs after the payment of the issue fee (there is no issue fee in reexamination), and thus 37 CFR 1.313(c) applies during the publication cycle for an application. Based on the statutory requirement for "special dispatch," the requirements for withdrawal of a reexamination proceeding from its publication cycle are at least as burdensome as those set forth in 37 CFR 1.313(b) and (c). **Accordingly, where a submission of patents and printed publications, or other information described in 37 CFR 1.98(a), is made while a proceeding is in its publication cycle, the patent owner must provide an unequivocal statement as to why the art submitted makes at least one claim unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable.** This is in addition to the above-discussed

(A) a factual accounting providing a sufficient explanation of why the information submitted could not have been submitted earlier. The submission of patents and printed publications must be accompanied by a petition under 37 CFR 1.182 (with petition fee) for withdrawal of the reexamination proceeding from the publication process for entry and consideration of the information submitted by patent owner. A grantable petition must provide the requisite showing discussed in this paragraph. (Emphasis added)

In the present instance, the fact situation fails to satisfy the grounds for the entry of information after issuance of a NIRC and the proceeding has entered the printing cycle. The instant petition was filed very late in the reexamination proceeding, and it fails to provide any statement as to why the submitted IDS items of information (art citations) make at least one claim unpatentable. Nor has patent owner filed an amendment to the claim or claims with an explanation as to how the amendment causes such claim or claims to be patentable. Contrary to the explanation of requirements for entry and consideration of an IDS after NIRC, patent owner states the information submitted does not render any claim unpatentable.¹ Furthermore, there is no factual accounting providing a sufficient explanation as to why the information submitted could not have been submitted earlier in the reexamination proceeding. There is no showing as to when patent owner first became aware of the existence of the items of information now being submitted, and no explanation as to why the information could not have been submitted earlier. In light of this lack of a factual accounting as to why the information could not have been submitted earlier, in addition to the lack of any amendment with the requisite explanation, petitioner has not satisfied the requirements for consideration of information submitted after NIRC when a proceeding has entered the print cycle. Therefore, the present petition does not satisfy the requirements for a petition submitted for consideration of IDS after a NIRC has been mailed and the proceeding has entered the print cycle.

For *ex parte* reexamination, 35 U.S.C. 305 provides that all *ex parte* reexamination proceedings "will be conducted with special dispatch within the Office." It is required that the withdrawal criteria of 37 CFR 1.313(c) be complied with for an application, in which there is no statutory provision for special dispatch, and such criteria must certainly be complied with for a reexamination proceeding *where there is a statutory mandate for special dispatch*. This is explicitly set forth in the MPEP, as set forth above.

A review of the record shows that the examiner terminated prosecution on the merits by issuing a NIRC on March 28, 2011, and the proceeding has now entered the final stages of the publication process, *i.e.* the print cycle, as evidenced by the proceeding's 452 status. The proceeding is clearly not scheduled to come up for further action on the merits. In order to provide the requested relief, the present proceeding would need to be withdrawn from the publication process, thus significantly regressing the processing of the proceeding. This would run contrary to the statutory requirement of 35 U.S.C. 305 that "[a]ll reexamination proceedings under this section...will be conducted with special dispatch within the Office." The statutory mandate of special dispatch is based upon the public interest in providing certainty and finality as to the question of patentability raised by a request for reexamination. In view of the submission of the IDS information after termination of the prosecution in this reexamination proceeding, the failure to explain why it could not have been submitted earlier, the failure to identify a question of patentability of the claims, and the failure to provide the requisite discussion (explanation) of the submitted art citations, the present reexamination proceeding will not be reopened at this late date to consider the proffered IDS papers.

¹ See petition at page 2.

Patent Owner Argument:

In this instance, the patent owner is arguing that the prior waiver for filing a 37 CFR 1.530 statement entitles patent owner to entry of the materials at issue, because waiver of the patent owner statement permitted issuance of a NIRC closing prosecution in less than two months from the date the Office issues an order granting reexamination. However, that argument does not change the fact that, in order to provide the requested relief, the present proceeding would need to be withdrawn from the publication process, thus significantly regressing the processing of the proceeding, which would run contrary to the statutory requirement of 35 U.S.C. 305 for special dispatch in reexamination. A patent owner that waives 37 CFR 1.530 is on notice via MPEP 2256 that if a NIRC issues, patent owner must provide the requisite showing to obtain consideration of a post NIRC IDS submission. Thus, by waiving the 37 CFR 1.530 statement patent owner assumed the risk that a NIRC closing prosecution may issue in under two months from the order date, which could affect the entry right for information.

The patent owner also argues that 37 CFR 1.555(a) does not provide an entry time period for IDS submissions in reexamination proceedings, as compared to 37 CFR 1.97 for applications. However, in view of the statutory requirement of 35 U.S.C. 305 for special dispatch in reexamination, there is no provision in the rules providing for entry of an IDS after a NIRC closes prosecution. A patent owner may resort to 37 CFR 1.182; however § 1.182 provides:

All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director, **subject to such other requirements as may be imposed...**(emphasis added)

In this instance, "such other requirements as may be imposed" are the MPEP 2256 requirements for the showing which patent owner must successfully provide in order to obtain consideration of a post NIRC IDS submission.

As a final point, *Hicks v. Costello*, 1903 Dec. Comm'r Pat 123, 125 (1903), addressing old Rule 213 directed to cases not specifically provided for in the rules, provided that such relief is not a mechanism for avoiding the requirements of the established rules and procedures, and is available only in extraordinary circumstances. If the patent owner in fact believes that one or more references submitted raises a substantial question of patentability as to at least one claim of the patent *different* than raised in this proceeding, the patent owner can always obtain relief via the rules by filing a new request for reexamination for consideration of such reference(s).

In view of all of the above, the petition is dismissed as to the request for consideration of the IDS papers. The proceeding will not be withdrawn from the publication process. The IDS submitted by patent owner will be placed in the file, and will remain of record. However, since prosecution has been terminated for this reexamination proceeding, the IDS will not be considered by the examiner.

In view of the above, the petition is dismissed.

CONCLUSION

1. The petition is dismissed as to the request to consider the IDS filed on April 28, 2011.

2. The IDS papers have not been entered for consideration by the examiner. A copy of the IDS submission will, however, be placed in the electronic file for the proceeding.
3. The present proceeding will continue in the publication process, toward issuance of a reexamination certificate.
4. Telephone inquiries related to this decision should be directed to Joseph F. Weiss, Jr., Legal Advisor, at (571) 272-7759.

/Kenneth M. Schor/

Kenneth M. Schor
Senior Legal Advisor
Office of Patent Legal Administration

EXHIBIT 15

Manual of PATENT EXAMINING PROCEDURE

Original Eighth Edition, August 2001

Latest Revision July 2010



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United States Patent and Trademark Office

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Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

First Edition, November 1949
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Third Edition, November 1961
Fourth Edition, June 1979
Fifth Edition, August 1983
Sixth Edition, January 1995
Seventh Edition, July 1998
Eighth Edition, August 2001
Revision 1, February 2003
Revision 2, May 2004
Revision 3, August 2005
Revision 4, October 2005
Revision 5, August 2006
Revision 6, September 2007
Revision 7, July 2008
Revision 8, July 2010

3. This form paragraph must be followed by form paragraph 7.28, where the amendment is made to the specification and/or drawings and introduces new matter into the disclosure, and/or form paragraph 7.31.01, where the amendment adds new matter to the claims or affects the claims.

4. If the amendment is an after-final amendment, an advisory action should be issued indicating that the amendment raises new issues because it is not in compliance with 37 CFR 1.57(a).

5. This form paragraph should not be used if there is an express incorporation by reference since applicant would not need to comply with the requirements of 37 CFR 1.57(a).

<

202 Cross-Noting

**

202.02 Notation in File History Regarding Prior U.S. Applications, Including Provisional Applications [R-3]

For Image File Wrapper (IFW) processing, see the IFW Manual.**>The front page of a printed patent identifies all prior applications for which benefits are claimed under 35 U.S.C. 119(e), 120, 121, or 365(c) in continuation-in-part, continuation, divisional, substitute, and reissue applications. Therefore, the identifying data of all prior applications for which benefits are claimed should be reviewed by the examiner to ensure that the data is accurate and provided in either the first sentence(s) of the specification or in an application data sheet. See 37 CFR 1.78(a) and MPEP § 201.11. For example, the reference to a prior nonprovisional application must include the appropriate relationship (e.g., continuation, divisional, or continuation-in-part) between the nonprovisional applications.<

The *>front page< of a printed patent issuing on a continued prosecution application (CPA) filed under 37 CFR 1.53(d) will identify the application number and filing date of the most recent noncontinued prosecution application (but not the filing date of the CPA) as well as all **>prior applications< from which *>benefit< was claimed in the most recent noncontinued prosecution application.

Where ** prior application data, including provisional application data, is preprinted ** on the PALM bib-data sheet **, the examiner should check that data for accuracy, including whether the application is, in fact, copending with the *>prior< nonprovisional

application or applications *>for< which *>benefit< is claimed. >Similarly, the application number of any provisional application for which benefit is claimed should be printed on the PALM bib-data sheet.< If applicant claims benefit under 35 U.S.C. 119(e) to a prior provisional application, and states that the provisional application claims priority to earlier domestic or foreign application(s), the earlier application(s) should not be reflected on the ** PALM bib-data sheet because a provisional application is not entitled to the right of priority of any other application. See 35 U.S.C. 111(b)(7).

Where the data is correct, the examiner should initial ** the PALM bib-data sheet ** in the provided space. Should there be error in the preprinted *>prior< application data, the ** correction or entry of the data in the PALM data base can be made by technical support staff of the Technology Center. Upon entry of the data, a new PALM bib-data sheet should be printed and **>scanned into< the file.

**

The inclusion of ** prior application information in the *>patent< does not necessarily indicate that the claims are entitled to the benefit of the earlier filing date.

See MPEP § 306 for work done by the Assignment Division pertaining to these particular types of applications.

In the situation in which there has been no reference to a *>prior< application because the benefit of its filing date is not desired, no notation as to the *>prior< application is made on the ** PALM bib-data sheet **.

202.03 Notation on File Wrapper When Priority Is Claimed for Foreign Application [R-3]

For Image File Wrapper (IFW) processing, see the IFW Manual. A ** PALM bib-data sheet should include the application number, country (or intellectual property authority), day, month, and year of each foreign application that the U.S. application is claiming the *>priority< of. The examiner should check this information for accuracy. Should there be error, the examiner should make the appropriate corrections directly ** on the PALM bib-data sheet, and have the information corrected in the Office computer systems by forwarding the information ** to the examiner's

siders other documents in Office search files while conducting a search of the prior art in a proper field of search.

(1) For e-IDS, use the e-IDS icon on examiner's workstation to consider cited U.S. patents and U.S. patent application publications. See MPEP § 609.07 for more information on e-IDS.

(2) Initial the blank column next to the citation to indicate that the information has been considered by the examiner >, or use the alternative electronic signature method by inserting on each page of reference citations the phrase "All references considered except where lined through" along with the examiner's electronic initials, and providing the examiner's electronic signature on the final page of reference citations<.

(B) Draw a line through the citation to show that it has not been considered if the citation fails to comply with all the requirements of 37 CFR 1.97 and 37 CFR 1.98. - The examiner should inform applicant the reasons why a citation was not considered.

(C) Write "not considered" on an information disclosure statement if none of the information listed complies with the requirements of 37 CFR 1.97 and 37 CFR 1.98. - The examiner will inform applicant the reasons why the IDS was not considered by using form paragraphs 6.49 through 6.49.09.

(D) Sign and date the bottom of the IDS listing >, or use the alternative electronic signature method noted in item (A)(2) above<.

(E) Ensure that a copy of the IDS listing that is signed and dated by the examiner is entered into the file and mailed to applicant.

For discussion of electronic processing of IDS, see MPEP § 609.08.

609.02 Information Disclosure Statements in Continued Examinations or Continuing Applications [R-5]

>When filing a continuing application that claims benefit under 35 U.S.C. 120 to a parent application (other than an international application that designated the U.S.), it will not be necessary for the applicant to submit an information disclosure statement in the continuing application that lists the prior art cited by the examiner in the parent application unless the

applicant desires the information to be printed on the patent issuing from the continuing application (for continued prosecution applications filed under 37 CFR 1.53(d), see subsection A.1. below). The examiner of the continuing application will consider information which has been considered by the Office in the parent application.

When filing a continuing application that claims benefit under 35 U.S.C. 120 to an international application that designated the U.S. (see MPEP § 1895), it will be necessary for the applicant to submit an information disclosure statement complying with 37 CFR 1.97 and 1.98 in the continuing application listing the documents cited in the international search report and/or the international preliminary examination report of the international application if applicant wishes to ensure that the information be considered by the examiner in the continuing application.<

IDS IN CONTINUED EXAMINATIONS OR CONTINUING APPLICATIONS

A. *IDS That Has Been Considered (1) in the Parent Application, or (2) Prior to the Filing of a Request for Continued Examination (RCE)*

1. Continued Prosecution Applications (CPAs) Filed Under 37 CFR 1.53(d)

Information which has been considered by the Office in the parent application of a continued prosecution application (CPA) filed under 37 CFR 1.53(d) will be part of the file before the examiner and need not be resubmitted in the continuing application to have the information considered and listed on the patent.

2. Continuation Applications, Divisional Applications, or Continuation-in-Part Applications Filed Under 37 CFR 1.53(b)

The examiner will consider information which has been considered by the Office in a parent application when examining: (A) a continuation application filed under 37 CFR 1.53(b), (B) a divisional application filed under 37 CFR 1.53(b), or (C) a continuation-in-part application filed under 37 CFR 1.53(b). A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

609.05(b)

MANUAL OF PATENT EXAMINING PROCEDURE

citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Examiner Note:

If an IDS listing includes a copy of an initialed IDS listing from another application, the IDS listing would not comply with the requirements under 37 CFR 1.98(a)(1). This form paragraph is applicable for such an IDS submission.

¶ **6.49.09 Information Disclosure Statement Not Considered, No Explanation of Relevance of Non-English Language Information**

The information disclosure statement filed [1] fails to comply with 37 CFR 1.98(a)(3)(i) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each reference listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

**>

¶ **6.49.10 Information Disclosure Statement Not Considered, Non-acceptable Electronic Medium**

The information disclosure statement filed [1] was submitted on an electronic medium that was not acceptable. It has been placed in the application file, but the information referred to therein has not been considered. Note that U.S. patents, U.S. application publications, foreign patent documents and non-patent literature cited in an information disclosure statement may be electronically submitted in compliance with the Office Electronic Filing System (EFS) requirements.

Examiner Note:

This form paragraph may be used when the IDS that includes patents and non-patent literature documents is submitted on compact discs or any other electronic medium, except via EFS. Only tables, sequence listings, and program listings may be submitted on CDs. See 37 CFR 1.52(a) and (e).

<

¶ **6.51 Time for Completing Information Disclosure Statement**

The information disclosure statement filed on [1] does not fully comply with the requirements of 37 CFR 1.98(b) because: [2]. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above-mentioned omissions or corrections in the information disclosure statement. **NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b).** Failure to timely comply with this notice will result in the

above-mentioned information disclosure statement being placed in the application file with the non-complying information **not** being considered. See 37 CFR 1.97(i).

Examiner Note:

Use this form paragraph if an IDS complies with the timing requirements of 37 CFR 1.97 but part of the content requirements of 37 CFR 1.98(b) has been inadvertently omitted.

This practice does not apply where there has been a deliberate omission of some necessary part of an Information Disclosure Statement or where the requirements based on the time of filing the statement, as set forth in 37 CFR 1.97, have not been complied with.

609.05(b) Complying Information Disclosure Statements [R-7]

The information contained in information disclosure statements which comply with both the content requirements of 37 CFR 1.98 and the requirements, based on the time of filing the statement, of 37 CFR 1.97 will be considered by the examiner. Consideration by the examiner of the information submitted in an IDS means that the examiner will consider the documents in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. The initials of the examiner placed adjacent to the citations on the PTO/SB/08A and 08B or its equivalent mean that the information has been considered by the examiner to the extent noted above.

>In addition, the following alternative electronic signature method may be used by examiners in information disclosure statements to indicate whether the information has been considered. Examiners will no longer initial each reference citation considered, but will continue to strikethrough each citation not considered. Each page of reference citations will be stamped by the examiner with the phrase "All references considered except where lined through" along with the examiner's electronic initials, and the final page of reference citations will include the examiner's electronic signature. <

Examiners must consider all citations submitted in conformance with the rules, and their initials when placed adjacent to the considered citations on the list or in the boxes provided on a form PTO/SB/08A and 08B >(or the examiner may use the alternative electronic signature method noted above)< provides a clear record of which citations have been considered

EXAMINATION OF APPLICATIONS

706.02

rejection. The rationale for this is several-fold. It is not uncommon for a full text document to reveal that the document fully anticipates an invention that the abstract renders obvious at best. The converse may also be true, that the full text document will include teachings away from the invention that will preclude an obviousness rejection under 35 U.S.C. 103, when the abstract alone appears to support the rejection. An abstract can have a different effective publication date than the full text document. Because all patentability determinations are fact dependent, obtaining and considering full text documents at the earliest practicable time in the examination process will yield the fullest available set of facts upon which to determine patentability, thereby improving quality and reducing pendency.

When both the abstract and the underlying document qualify as prior art, the underlying document should normally be used to support a rejection. In limited circumstances, it may be appropriate for the examiner to make a rejection in a non-final Office action based in whole or in part on the abstract only without relying on the full text document. In such circumstances, the full text document and a translation (if not in English) may be supplied in the next Office action. Whether the next Office action may be made final is governed by MPEP § 706.07(a).

III. >RELIANCE ON ADMITTED PRIOR ART IN SUPPORT OF REJECTION

A statement by an applicant in the specification or made during prosecution identifying the work of another as “prior art” is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988). See MPEP § 2129 for discussion on admissions as prior art. Where the admitted prior art anticipates the claim but does not qualify as prior art under any of the paragraphs of 35 U.S.C. 102, the claim may be rejected as being anticipated by the admitted prior art without citing to 35 U.S.C. 102.

IV. < REEXAMINATION

For scope of rejections in *ex parte* reexamination proceedings, see MPEP § 2258 and in *inter partes* reexamination, see MPEP § 2658.

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V. < DISTINCTION BETWEEN 35 U.S.C. 102 AND 103

The distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made. See MPEP § 2131 - § 2146 for guidance on patentability determinations under 35 U.S.C. 102 and 103.

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VI. < DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION

The effective filing date of a U.S. application may be determined as follows:

(A) If the application is a continuation or divisional of one or more earlier U.S. applications or international applications and if the requirements of 35 U.S.C. 120 and 365(c), respectively, have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.

(B) If the application is a continuation-in-part of an earlier U.S. application or international application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application. Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application.

706.02(a)

MANUAL OF PATENT EXAMINING PROCEDURE

(C) If the application claims foreign priority under 35 U.S.C. 119(a)-(d) or 365(a) or (b), the effective filing date is the filing date of the U.S. application, unless situation (A) or (B) as set forth above applies. The filing date of the foreign priority document is not the effective filing date, although the filing date of the foreign priority document may be used to overcome certain references. See MPEP § 706.02(b) and § 2136.05.

(D) If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.

See MPEP § 1893.03(b) for determining the effective filing date of an application under 35 U.S.C. 371. See MPEP § 201.11(a) and § 1895 for additional information on determining the effective filing date of a continuation, divisional, or continuation-in-part of a PCT application designating the U.S. See also MPEP § 1895.01 and § 1896 which discuss differences between applications filed under 35 U.S.C. 111(a) and international applications that enter national stage under 35 U.S.C. 371.

706.02(a) Rejections Under 35 U.S.C. 102(a), (b), or (e); Printed Publication or Patent [R-3]

Once the examiner conducts a search and finds a printed publication or patent which discloses the claimed invention, the examiner should determine whether the rejection should be made under 35 U.S.C. 102(a), (b), or (e).

In order to determine which section of 35 U.S.C. 102 applies, the effective filing date of the application must be determined and compared with the date of the reference. See MPEP § 706.02 regarding determination of effective filing date of the application.

I. DETERMINING THE REFERENCE ISSUE OR PUBLICATION DATE

The examiner must determine the issue or publication date of the reference so that a proper comparison between the application and reference dates can be made. A magazine is effective as a printed publication under 35 U.S.C. 102(b) as of the date it reached the

addressee and not the date it was placed in the mail. *Protein Foundation Inc. v. Brenner*, 260 F. Supp. 519, 151 USPQ 561 (D.D.C. 1966). See MPEP § 707.05(f). For foreign patents see MPEP § 901.05. See MPEP § 2124, § 2126, and § 2128 - § 2128.02 for case law relevant to reference date determination.

II. DETERMINING WHETHER TO APPLY 35 U.S.C. 102(a), (b), or (e)

A. 35 U.S.C. 102(b)

First, the examiner should consider whether the reference qualifies as prior art under 35 U.S.C. 102(b) because this section results in a statutory bar to obtaining a patent. If the publication or issue date of the reference is more than 1 year prior to the effective filing date of the application (MPEP § 706.02), the reference qualifies as prior art under 35 U.S.C. 102(b).

Where the last day of the year dated from the date of publication falls on a Saturday, Sunday or Federal holiday, the publication is not a statutory bar under 35 U.S.C. 102(b) if the application was filed on the next succeeding business day. *Ex parte Olah*, 131 USPQ 41 (Bd. App. 1960) (The Board in *Olah* held that 35 U.S.C. 21(b) is applicable to the filing of an original application for patent and that applicant's own activity will not bar a patent if the 1-year grace period expires on a Saturday, Sunday, or Federal holiday and the application's U.S. filing date is the next succeeding business day.) Despite changes to 37 CFR 1.6(a)(2) and 1.10 which permit the USPTO to accord a filing date to an application as of the date of deposit as "Express Mail" with the U.S. Postal Service in accordance with 37 CFR 1.10 (e.g., a Saturday filing date), the rule changes do not affect applicant's concurrent right to defer the filing of an application until the next business day when the last day for "taking any action" falls on a Saturday, Sunday, or Federal holiday (e.g., the last day of the 1-year grace period falls on a Saturday).

B. 35 U.S.C. 102(e)

If the publication or issue date of the reference is too recent for 35 U.S.C. 102(b) to apply, then the examiner should consider 35 U.S.C. 102(e).

In order to apply a reference under 35 U.S.C. 102(e), the inventive entity of the application must be

EXHIBIT 16

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

-----x
KFX MEDICAL CORP. :
Plaintiff and :
Counterdefendant, : Case No.
v. : 3:11-CV-01698
ARTHREX, INC. : DMS-BLM
Defendant and :
Counterclaimant. :
-----x

CONFIDENTIAL - FOR COUNSEL ONLY

Videotaped Deposition of
KFX MEDICAL CORPORATION,
By and through its Designated Representative,
RYAN EDWARD MELNICK, PH.D.,
And in his Personlly Capacity
San Diego, California
Tuesday, December 4, 2012
9:04 a.m.

Job No.: 28539
Pages: 1 - 173
Reported by: Veronica S. Thompson, CSR 6056, RPR, CRR

CONFIDENTIAL VIDEOTAPED DEPOSITION OF RYAN EDWARD MELNICK, PH.D.
CONDUCTED ON TUESDAY, DECEMBER 4, 2012

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1	that correct?	01:50:40
2	A. Yes.	01:50:41
3	Q. Why did you include the Scott statement in this	01:50:42
4	IDS?	01:50:45
5	MR. BENNETT: Objection. Privileged.	01:50:45
6	Instructing the witness not to answer.	01:50:47
7	BY MR. HERRMAN:	01:50:50
8	Q. Do you have an answer to that question that you	01:50:50
9	would provide if you had not been instructed not to	01:50:52
10	answer?	01:50:55
11	A. Yes.	01:50:55
12	Q. On page 32507, where it lists the statement of	01:51:07
13	Tate Scott, it says, "Statement of Tate Scott Dated	01:51:13
14	April 12, 2011, Submitted in Reexamination Number	01:51:17
15	90/011430."	01:51:20
16	Why does it say "Submitted in Reexamination	01:51:28
17	Number 90/011430"?	01:51:30
18	MR. BENNETT: If you can -- can you reask the	01:51:45
19	question? Thank you.	01:51:47
20	BY MR. HERRMAN:	01:51:49
21	Q. Why does this IDS say that the statement of	01:51:50
22	Tate Scott was submitted in reexamination number	01:51:53
23	90/011430?	01:51:56
24	MR. BENNETT: I'll -- because -- I'll -- yeah,	01:52:02
25	you can -- you can answer that provided you don't reveal	01:52:04

CONFIDENTIAL VIDEOTAPED DEPOSITION OF RYAN EDWARD MELNICK, PH.D.
CONDUCTED ON TUESDAY, DECEMBER 4, 2012

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1	the substance of any privileged communications.	01:52:07
2	THE WITNESS: Because it was.	01:52:14
3	BY MR. HERRMAN:	01:52:16
4	Q. Did you have a reason for noting that this	01:52:21
5	statement was submitted in the reexamination?	01:52:23
6	MR. BENNETT: That's a yes-or-no question?	01:52:34
7	MR. HERRMAN: Yes.	01:52:37
8	MR. BENNETT: You can answer yes or no on that,	01:52:43
9	yeah.	01:52:45
10	THE WITNESS: Yes.	01:52:45
11	BY MR. HERRMAN:	01:52:45
12	Q. For all of the other references that are	01:52:49
13	submitted in this and other IDSs that were also submitted	01:52:51
14	in reexaminations, do you always note that the references	01:52:55
15	were submitted in a previous reexamination?	01:53:00
16	MR. BENNETT: Objection. That's vague and	01:53:05
17	ambiguous.	01:53:08
18	THE WITNESS: No.	01:53:13
19	BY MR. HERRMAN:	01:53:14
20	Q. Why not?	01:53:15
21	MR. BENNETT: Are you -- if -- can I make sure	01:53:19
22	I understand the question?	01:53:24
23	You're asking him why the -- why other	01:53:24
24	references did not have an indication?	01:53:32
25	MR. HERRMAN: I'm asking him -- let me -- let	01:53:36

CONFIDENTIAL VIDEOTAPED DEPOSITION OF RYAN EDWARD MELNICK, PH.D.
CONDUCTED ON TUESDAY, DECEMBER 4, 2012

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1	Q. Why didn't KFx tell the examiner in the	01:56:35
2	620 application that the Scott statement had not been	01:56:37
3	considered during the reexamination?	01:56:40
4	MR. BENNETT: Objection. It's privileged.	01:56:42
5	Instructing the witness not to answer.	01:56:45
6	BY MR. HERRMAN:	01:56:52
7	Q. Do you have an answer that you would provide if	01:56:52
8	you were not being instructed not to answer?	01:56:54
9	A. Yes.	01:56:56
10	Q. If you were the examiner -- if you were the	01:57:05
11	examiner in the 620 application, would you think that it	01:57:07
12	was important that the Scott statement was not considered	01:57:10
13	during the reexamination?	01:57:13
14	MR. BENNETT: Objection. Improper	01:57:15
15	hypothetical. It's opinion testimony from a lay witness	01:57:18
16	who's not an expert that's been designated in this case,	01:57:22
17	and the question is vague.	01:57:25
18	THE WITNESS: Could you repeat the question	01:57:28
19	again? Sorry.	01:57:29
20	BY MR. HERRMAN:	01:57:30
21	Q. If you were the examiner, would you think it	01:57:30
22	was important to know that the Scott statement had not	01:57:32
23	been considered during the reexamination?	01:57:37
24	A. No.	01:57:41
25	Q. Why not?	01:57:41

CONFIDENTIAL VIDEOTAPED DEPOSITION OF RYAN EDWARD MELNICK, PH.D.
CONDUCTED ON TUESDAY, DECEMBER 4, 2012

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1	A. Because as an examiner, it would be my duty to	01:57:44
2	consider every item of information submitted in an	01:57:47
3	information disclosure statement.	01:57:51
4	Q. Whether or not it had been submitted in a	01:57:56
5	reexamination?	01:57:58
6	A. Correct.	01:57:59
7	Q. The examiner in the 620 application would not	01:58:07
8	have any reason to believe that the Scott statement was	01:58:09
9	not considered during the reexamination. Is that	01:58:12
10	correct?	01:58:15
11	MR. BENNETT: Objection. Calls for	01:58:18
12	speculation, and it's vague.	01:58:19
13	THE WITNESS: What is the question again?	01:58:23
14	BY MR. HERRMAN:	01:58:25
15	Q. The examiner in the 620 application would not	01:58:25
16	have any reason not to believe that the Scott statement	01:58:28
17	had not been considered during the reexamination.	01:58:35
18	Correct?	01:58:38
19	A. There's a lot of negatives there.	01:58:39
20	MR. BENNETT: Objection. Vague and ambiguous.	01:58:42
21	If you understand, then -- the question,	01:58:44
22	answer.	01:58:49
23	THE WITNESS: I don't think the examiner would	01:58:53
24	have any reason to think that it was considered.	01:58:54
25	///	01:58:57

CONFIDENTIAL VIDEOTAPED DEPOSITION OF RYAN EDWARD MELNICK, PH.D.
CONDUCTED ON TUESDAY, DECEMBER 4, 2012

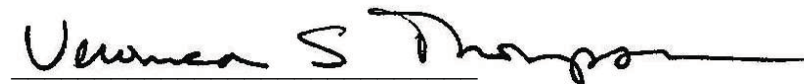
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REPORTER'S CERTIFICATE

I, Veronica S. Thompson, Certified Shorthand
Reporter for the State of California, do hereby certify:

That the witness named in the foregoing
deposition was by me duly sworn; that the deposition was
then taken before me at the time and place herein set
forth; that the testimony and proceedings were reported
stenographically by me and were transcribed through
computerized transcription by me; that the foregoing is a
true record of the testimony and proceedings taken at
that time; and that I am not interested in the event of
the action.

Witness my hand dated December 10, 2012.



Veronica S. Thompson

CSR 6056, RPR, CRR

EXHIBIT 17

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 1 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	3,623,192	11-30-1971	Button	
	2	4,210,148	07-01-1980	Stivala	
	3	4,532,926	08-06-1985	O'Holla	
	4	4,796,612	01-10-1989	Reese	
	5	4,898,156	02-06-1990	Gattorna et al.	
	6	5,013,316	05-07-1991	Goble et al.	
	7	5,192,303	03-09-1993	Gattorna et al.	
	8	5,219,359	06-15-1993	McQuilkin et al.	
	9	5,224,946	07-06-1993	Hayhurst et al.	
	10	5,269,784	12-14-1993	Mast	
	11	5,336,240	08-09-1994	Metzler et al.	
	12	5,372,604	12-13-1994	Trott	
	13	5,417,712	05-23-1995	Whittaker et al.	
	14	5,423,858	06-13-1995	Bolanos et al.	
	15	5,423,860	06-13-1995	Lizardi et al.	
	16	5,472,452	12-05-1995	Trott	
	17	5,478,353	12-26-1995	Yoon	
	18	5,500,001	03-19-1996	Trott	
	19	5,527,341	06-18-1996	Gogolewski et al.	
	20	5,527,343	06-18-1996	Bonutti	
	21	5,543,012	08-06-1996	Watson et al.	
	22	5,545,180	08-13-1996	Le et al.	
	23	5,569,306	10-29-1996	Thal	
	24	5,575,801	11-19-1996	Habermeyer et al.	
	25	5,578,057	11-26-1996	Wenstrom, Jr.	
	26	5,584,835	12-17-1996	Greenfield	
	27	5,591,207	01-07-1997	Coleman	
	28	5,634,926	06-03-1997	Jobe	
	29	5,683,419	11-04-1997	Thal	

Examiner Signature /Gregory Anderson/	Date Considered 12/02/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 2 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	5,690,676	11-25-1997	DiPoto et al.	
	31	5,697,950	12-16-1997	Fucci et al.	
	32	5,720,765	02-24-1998	Thal	
	33	5,725,557	03-10-1998	Gattuma	
	34	5,769,894	06-23-1998	Ferragamo	
	35	5,800,436	09-01-1998	Lerch	
	36	5,814,072	09-29-1998	Bonutti	
	37	5,891,168	04-06-1999	Thal	
	38	5,948,001	09-07-1999	Larsen	
	39	5,948,002	09-07-1999	Bonutti	
	40	5,951,590	09-14-1999	Goldfarb	
	41	5,964,769	10-12-1999	Wagner et al.	
	42	6,010,525	01-04-2000	Bonutti et al.	
	43	6,013,077	01-11-2000	Harwin	
	44	6,013,083	01-11-2000	Bennett	
	45	6,027,523	02-22-2000	Schmieding	
	46	6,045,573	04-04-2000	Wenstrom, Jr. et al.	
	47	6,056,751	05-02-2000	Fenton, Jr.	
	48	6,063,106	05-16-2000	Gibson	
	49	6,093,201	07-25-2000	Cooper et al.	
	50	6,093,301	07-25-2000	Van Atta	
	51	6,099,547	08-08-2000	Gellman et al.	
	52	6,110,207	08-29-2000	Eichhorn et al.	
	53	6,117,160	09-12-2000	Bonutti	
	54	6,117,161	09-12-2000	Li et al.	
	55	6,126,677	10-03-2000	Ganaja et al.	
	56	6,149,669	11-21-2000	Li	
	57	6,200,330 B1	03-13-2001	Benderev et al.	
	58	6,241,749 B1	06-05-2001	Rayhanabad	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

T¹ - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 3 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,245,082 B1	06-12-2001	Gellman et al.	
	60	6,280,474 B1	08-28-2001	Cassidy et al.	
	61	6,293,961 B2	09-25-2001	Schwartz et al.	
	62	6,296,659 B1	10-02-2001	Foerster	
	63	6,306,159 B1	10-23-2001	Schwartz et al.	
	64	6,319,271 B1	11-20-2001	Schwartz et al.	
	65	6,328,758 B1	12-11-2001	Tornier et al.	
	66	6,391,030 B1	05-21-2002	Wagner et al.	
	67	6,423,065 B2	07-23-2002	Ferree	
	68	6,432,123 B1	08-13-2002	Schwartz et al.	
	69	6,464,713 B2	10-15-2002	Bonutti	
	70	6,491,714 B1	12-10-2002	Bennett	
	71	6,514,274 B1	02-04-2003	Boucher et al.	
	72	6,518,200 B2	02-11-2003	Lin	
	73	6,520,980 B1	02-18-2003	Foerster	
	74	6,524,317 B1	02-25-2003	Ritchart et al.	
	75	6,527,794 B1	03-04-2003	McDevitt et al.	
	76	6,533,795 B1	03-18-2003	Tran et al.	
	77	6,540,770 B1	04-01-2003	Tornier et al.	
	78	6,547,800 B2	04-15-2003	Foerster et al.	
	79	6,551,330 B1	04-22-2003	Bain et al.	
	80	6,554,852 B1	04-29-2003	Oberländer	
	81	6,569,187 B1	05-27-2003	Bonutti et al.	
	82	6,575,987 B2	06-10-2003	Gellman et al.	
	83	6,582,453 B1	06-24-2003	Tran et al.	
	84	6,585,730 B1	07-01-2003	Foerster	
	85	6,605,096 B1	08-12-2003	Ritchart	
	86	6,635,073 B2	10-21-2003	Bonutti	
	87	6,638,279 B2	10-28-2003	Bonutti	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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Receipt date: 12/01/2011

13245620 - GAU: 3773

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 4 OF 8	Attorney Docket No.	KFX.003C1

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Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,641,597 B2	11-04-2003	Burkhart et al.	
	89	6,652,561 B1	11-25-2003	Tran	
	90	6,660,008 B1	12-09-2003	Foerster et al.	
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	92	6,673,094 B1	01-06-2004	McDevitt et al.	
	93	6,712,830 B2	03-30-2004	Esplin	
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	95	6,780,198 B1	08-24-2004	Gregoire et al.	
	96	6,855,157 B2	02-15-2005	Foerster et al.	
	97	6,984,241 B2	01-10-2006	Lubbers et al.	
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	99	7,001,411 B1	02-21-2006	Dean	
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SHEET 5 OF 8	Attorney Docket No.	KFX.003C1

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	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 6 OF 8	Attorney Docket No.	KFX.003C1

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Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
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	170	WO 1999/052478 A1	10-21-1999	Axya Medical, Inc.		

Examiner Signature /Gregory Anderson/	Date Considered 12/02/2011
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Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 7 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹	
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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 8 OF 8	Attorney Docket No.	KFX.003C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
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EXHIBIT 18

Receipt date: 12/01/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 2 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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SHEET 3 OF 8		Attorney Docket No.	KFX.003C2

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	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

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EXHIBIT 18

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 5 OF 8	Attorney Docket No.	KFX.003C2

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
SHEET 6 OF 8		Examiner Gregory A. Anderson
		Attorney Docket No. KFX.003C2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 7 OF 8	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 8 OF 8	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

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EXHIBIT 18

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EXHIBIT 19



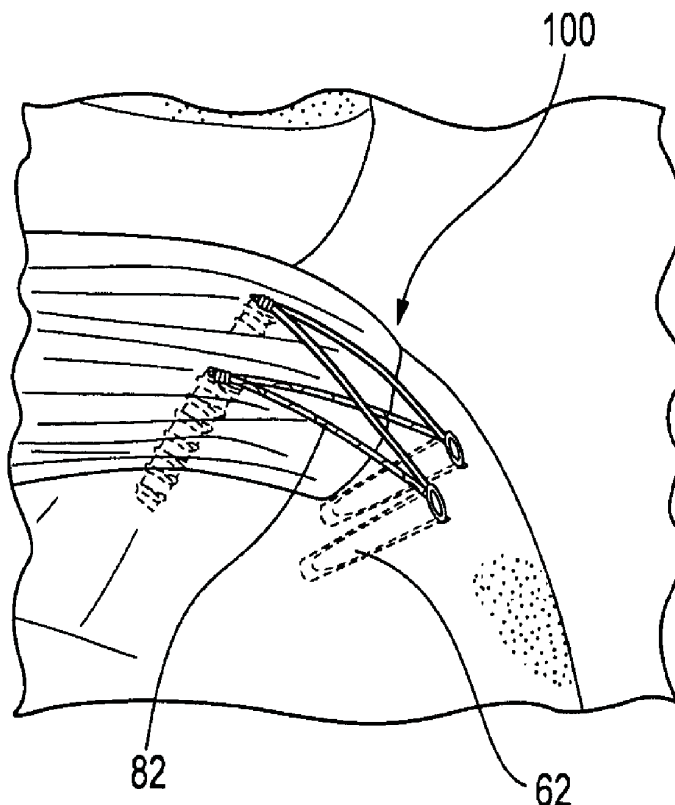
US 20070191849A1

(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0191849 A1**
ElAttrache et al. (43) **Pub. Date: Aug. 16, 2007**(54) **METHOD FOR DOUBLE ROW FIXATION OF TENDON TO BONE****Publication Classification**(76) Inventors: **Neal S. ElAttrache**, Los Angeles, CA (US); **James E. Tibone**, Los Angeles, CA (US)(51) **Int. Cl.**
A61B 17/58 (2006.01)
(52) **U.S. Cl.** **606/72**Correspondence Address:
DICKSTEIN SHAPIRO LLP
1825 EYE STREET NW
Washington, DC 20006-5403 (US)(57) **ABSTRACT**

A system and method for soft tissue to bone repair employing at least one suture anchor combined with at least one knotless fixation device. The method for soft tissue to bone fixation includes: (i) providing a first medial row constructed with a first plurality of fixation devices, at least one of the first plurality of fixation devices is an anchor; and (ii) providing a second lateral row constructed with a second plurality of fixation devices, at least one of the second plurality of fixation devices is a knotless fixation device, and suture or tape or allograft/biological component extending over the soft tissue and secured in place by the anchors in the first and second medial rows.

(21) Appl. No.: **11/700,916**(22) Filed: **Feb. 1, 2007****Related U.S. Application Data**

(60) Provisional application No. 60/763,915, filed on Feb. 1, 2006.



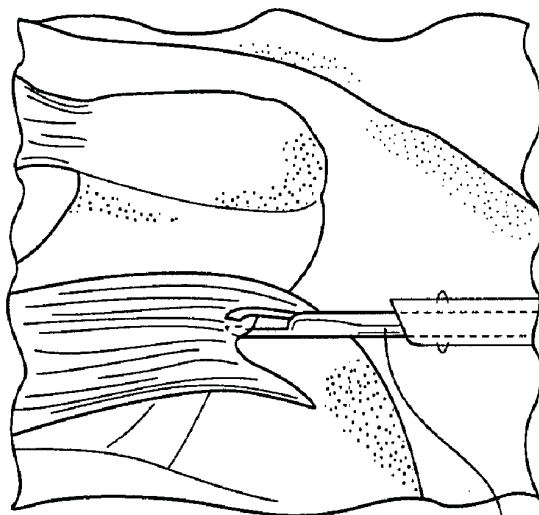


FIG. 1

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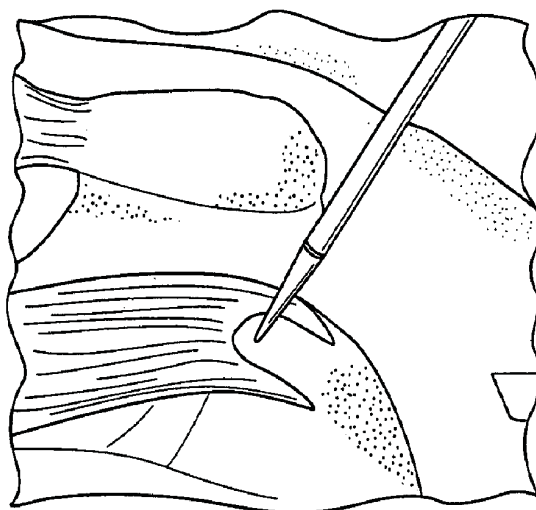


FIG. 2

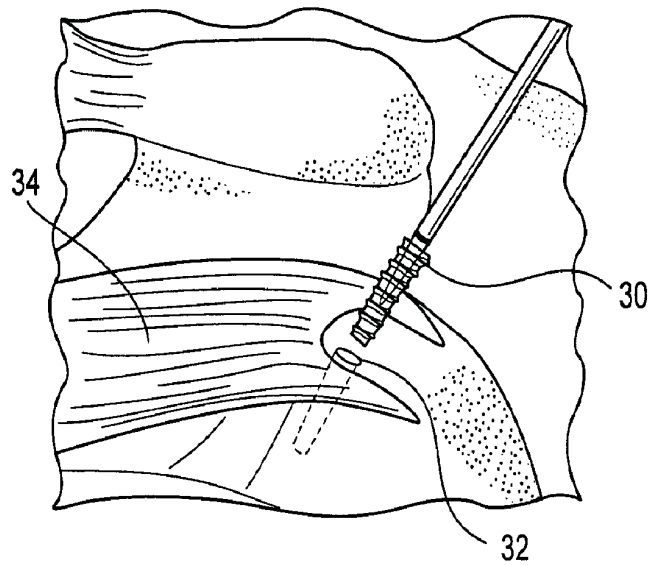


FIG. 3

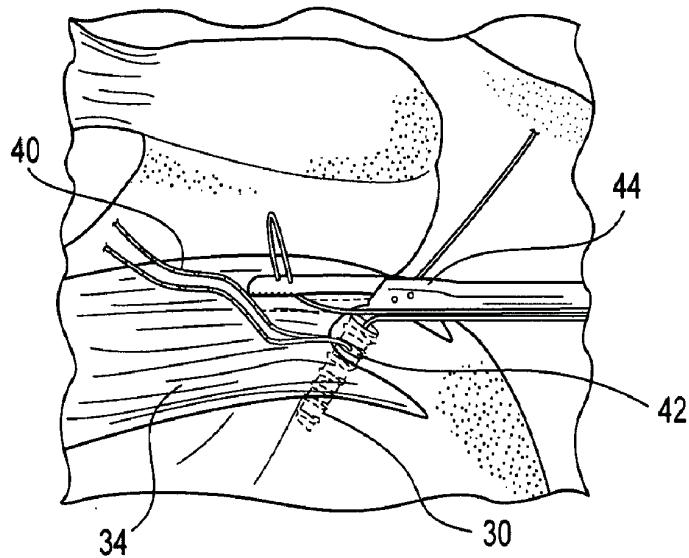


FIG. 4

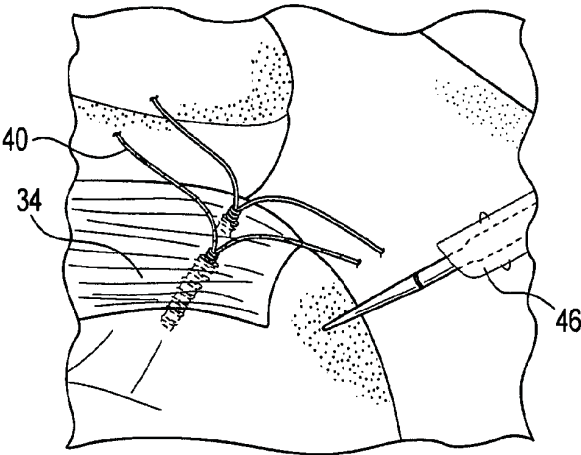


FIG. 5

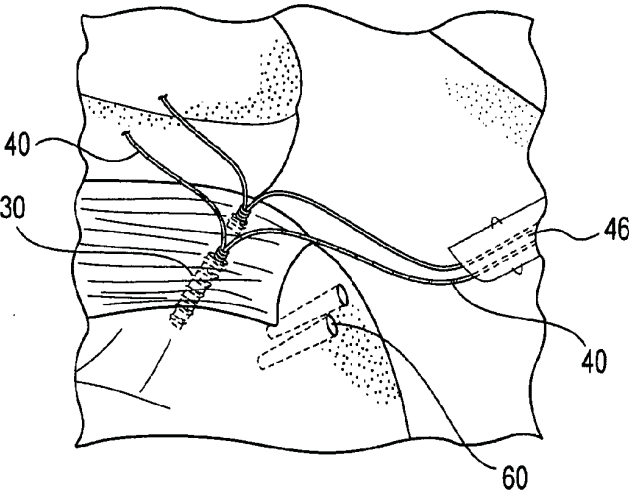


FIG. 6

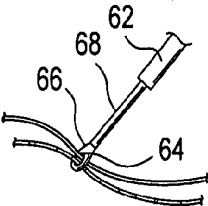


FIG. 6a

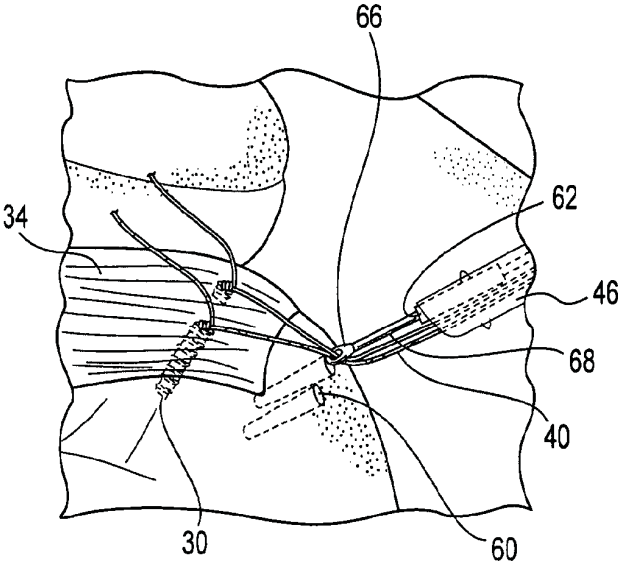


FIG. 7

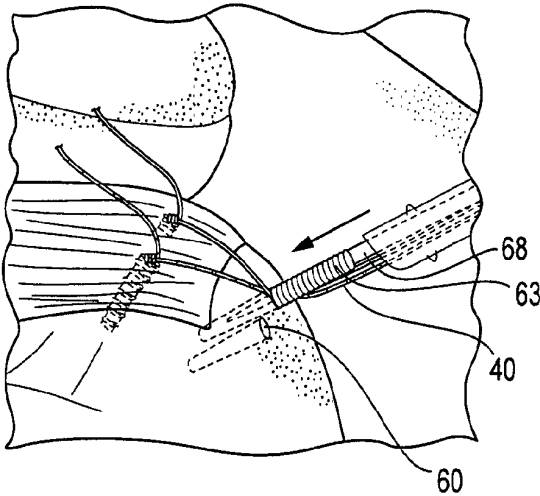


FIG. 8

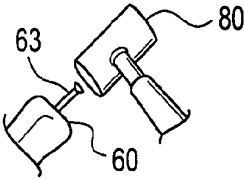


FIG. 8a

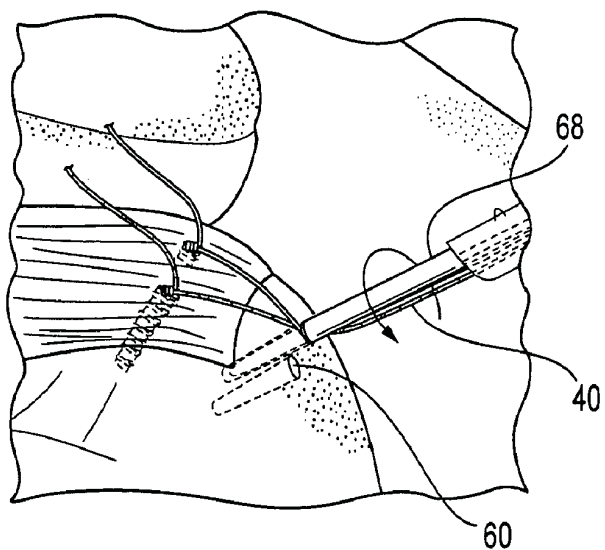


FIG. 9

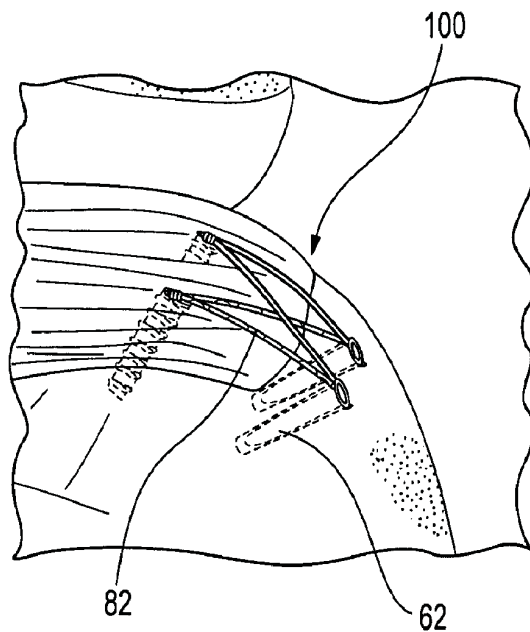


FIG. 10

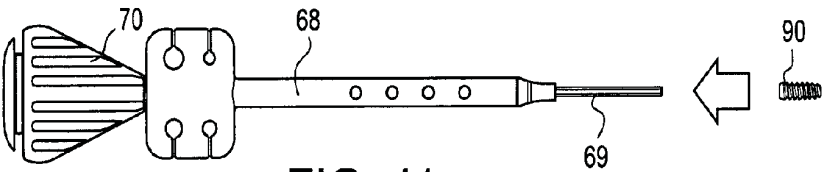


FIG. 11a

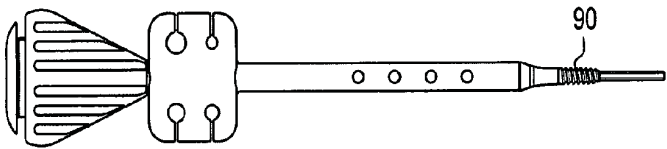


FIG. 11b

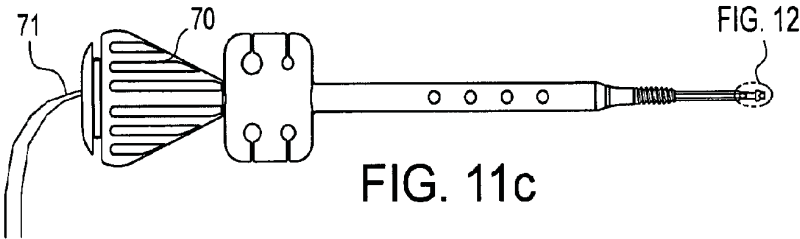


FIG. 11c

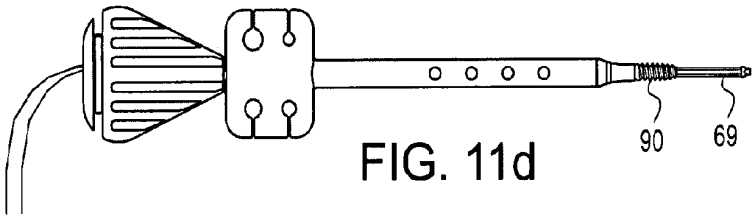


FIG. 11d

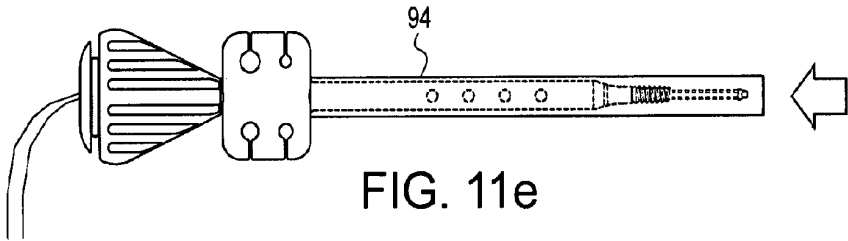


FIG. 11e

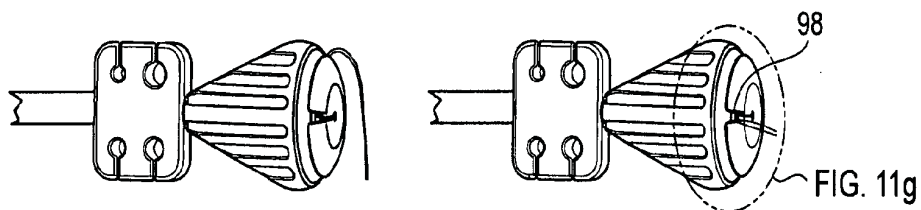


FIG. 11f

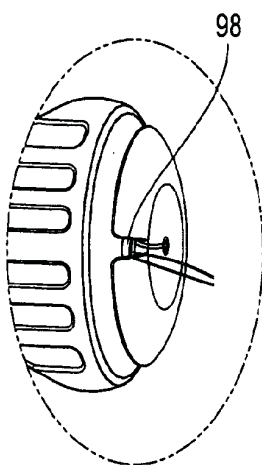


FIG. 11g

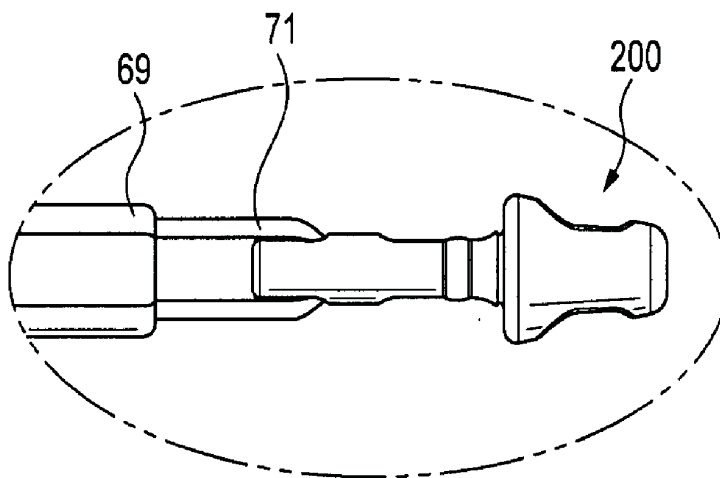


FIG. 12

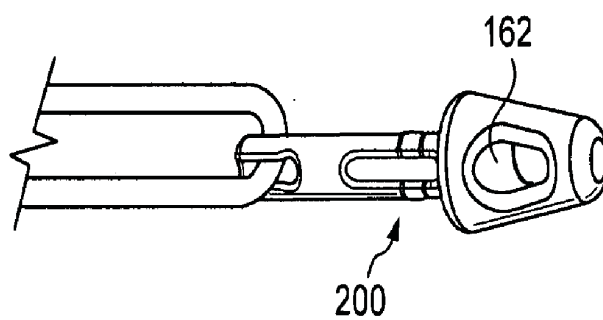


FIG. 13

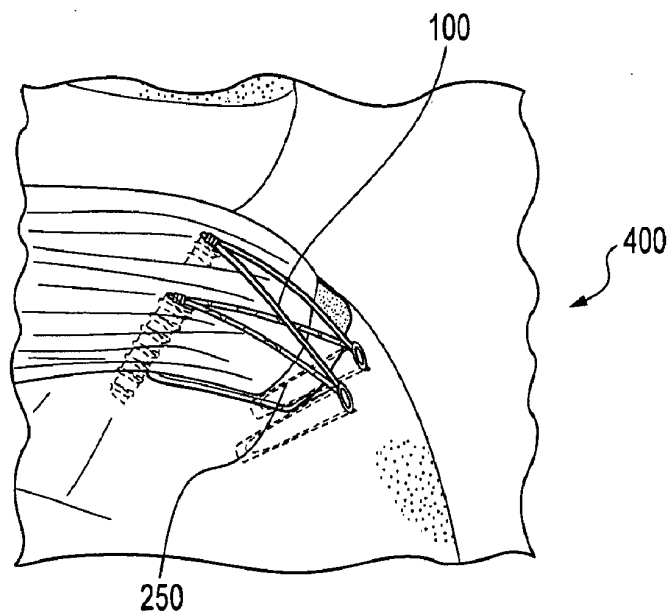


FIG. 14

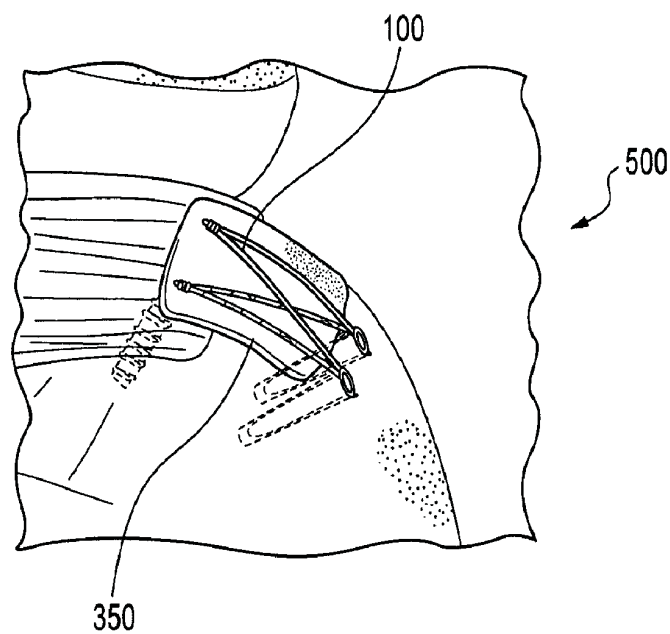


FIG. 15

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Aug. 16, 2007

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METHOD FOR DOUBLE ROW FIXATION OF TENDON TO BONE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/763,915, filed Feb. 1, 2006, the entire disclosure of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention relates to methods of arthroscopic surgery and, more specifically, to an improved method of attaching tissue to bone, such as rotator cuff repair.

BACKGROUND OF THE INVENTION

[0003] When soft tissue tears away from bone, reattachment becomes necessary. Various devices, including sutures, screws, staples, wedges, anchors and plugs have been used in the prior art to secure soft tissue to bone. Surgical methods utilizing suture anchors alone are disadvantageous for reattachment of large areas of detached tissue because they often do not allow good tissue to bone contact.

[0004] Reattachment of soft tissue to bone typically requires the surgeon to pass suture material through selected tissue, form a plurality of surgical knots extracorporeally and then move the knots into position adjacent the desired tissue to be sutured. In such procedures, the surgeon must manually tie the knots on the suture strands after the suture is threaded through the selected tissues to be sutured. Knot tying during surgery, particularly arthroscopic surgery, is tedious and time-consuming. There is also a tendency for the knots to deform or collapse as the surgeon manually forces the knots down into the proper position. Also, the suture knots often are exposed to abrasion or cutting by sharp or rough areas along the walls of the bone canal into which anchors are typically inserted to provide fixation of tendon to bone.

[0005] Accordingly, a need exists for an improved method for attaching soft tissue to bone which does not require multiple suture knots and which allows the tendon to remain securely in place until the ligaments naturally attach to bone. A method of threading suture through a tendon with maximum suture fixation strength, as well as a method of securing the tendon to bone that allows for accelerated tendon healing to bone are also needed.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention provides a system and method for soft tissue to bone repair employing at least one suture anchor combined with at least one knotless fixation device.

[0007] More specifically, the present invention provides a method for tendon to bone fixation which includes: (i) providing a first medial row constructed with a first plurality of fixation devices, at least one of the first plurality of fixation devices being an anchor; (ii) providing a second lateral row constructed with a second plurality of fixation devices, at least one of the second plurality of fixation devices being a knotless fixation device; and (iii) providing

a structure comprising an element selected from the group consisting of suture, tape and allograft/biological component, and extending the structure over the soft tissue so that the structure is secured in place by the anchors.

[0008] Other features and advantages of the present invention will become apparent from the following description of the invention, which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a side view illustrating an initial step of a method of arthroscopic rotator cuff repair according to an exemplary embodiment of the present invention.

[0010] FIG. 2 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 1.

[0011] FIG. 3 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 2.

[0012] FIG. 4 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 3.

[0013] FIG. 5 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 4.

[0014] FIG. 6 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 5.

[0015] FIG. 7 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 6.

[0016] FIG. 8 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 7.

[0017] FIG. 9 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 8.

[0018] FIG. 10 is a side view of the structure of FIG. 1 and at a step subsequent to that shown in FIG. 9.

[0019] FIGS. 11(a)-(g) illustrate various steps of assembling a driver with a swivel knotless fixation device employed during a knotless repair according to the present invention.

[0020] FIGS. 12 is a first enlarged side view of the swivel anchor implant illustrated in FIGS. 11(a)-(g).

[0021] FIG. 13 is a second enlarged side view of the swivel anchor implant of FIG. 12.

[0022] FIG. 14 is a side view of the structure of FIG. 1 according to a second exemplary embodiment of arthroscopic rotator cuff repair of the present invention.

[0023] FIG. 15 is a side view of the structure of FIG. 1 according to a third exemplary embodiment of arthroscopic rotator cuff repair of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Referring now to the drawings, where like elements are designated by like reference numerals, FIGS. 1 through 15 illustrate systems and methods of attaching a tendon to bone according to the present invention. For exemplary purposes only, the invention will be described below with reference to an arthroscopic rotator cuff repair. However, the invention is not limited to this exemplary embodiment and has applicability to any reattachment of soft tissue to bone.

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[0025] The methods of the present invention enhance footprint compression and allow for accelerated tendon healing to bone that is achieved with minimal knot tying. The repair consists of a tied medial row constructed with at least one suture anchor combined with knotless lateral fixation using at least one knotless fixation device. Preferably, the repair consists of a tied medial row constructed with two suture anchors (such as two Arthrex 5.5 mm Bio-Corkscrew® FT anchors, for example) combined with knotless lateral fixation using at least one knotless fixation device, preferably at least two knotless fixation devices (such as two Arthrex 3.5 mm PushLock™ anchors, two Arthrex SwiveLock™ anchors, a combination of the PushLock™ and SwiveLock™ anchors, or a combination of at least one of a PushLock™ and SwiveLock™ anchor with another knotless fixation device or with other fixation device, among others). The result is a quick, secure and low profile repair with excellent contact between tendon and bone.

[0026] FIG. 1 illustrates a side view of a human shoulder of a patient undergoing a rotator cuff repair in accordance with an exemplary embodiment of the present invention. Although this particular embodiment will be illustrated below with reference to FIGS. 1-10 and with reference to only a particular knotless fixation device (such as Arthrex "PushLock" anchor), the invention is not limited to this particular embodiment and contemplates additional embodiments wherein any knotless fixation device may be employed, depending on the characteristics of the repair site and of the particular application.

[0027] The patient may be positioned in the beach chair position using the Arthrex Beach Chair Lateral Traction Device or in a lateral decubitus position using the Arthrex 3-Point Shoulder Distraction System. Access to the subacromial space is facilitated with a variety of cannulas.

[0028] First, and as illustrated in FIG. 1, the mobility of the tear is assessed using, for example, a tissue grasper 10 such as the Arthrex KingFisher™ Suture Retriever/Tissue Grasper, to determine whether a U or L-shaped component exists. Where large tears extend to the superior aspect of the glenoid, margin convergence suturing is performed to reduce volume and strain on the repair. Subsequently, the length and width of the rotator cuff footprint is assessed and a bleeding bed for enhanced tendon to bone healing may be formed. This may be accomplished with a burr to perform a light dusting of the greater tuberosity, or by using a chondro pick to microfracture the footprint and maximize vascular channels.

[0029] FIG. 2 illustrates the preparation of two pilot holes for two suture anchors that will be inserted in the medial row. A punch may be employed adjacent to the articular margin of the humerus and at about 45° angle to form the two pilot holes.

[0030] Subsequent to the formation of the pilot holes, and as shown in FIG. 3, a suture anchor 30 is placed in the pre-formed hole 32. As shown in FIG. 4, two suture anchors 30 are placed in the two pre-formed holes 32 in a medial row. These anchors assure full contact of the detached tendon 34 along the medial footprint of the greater tuberosity. In an exemplary embodiment, at least one of the two suture anchors is a fully-threaded bioabsorbable suture anchor having a loop inserted into the suture anchor, and as

disclosed and described in U.S. patent application Ser. No. 11/224,060, filed on Sep. 13, 2005 and entitled "Fully-Threaded Bioabsorbable Suture Anchor," the disclosure of which is hereby incorporated by reference in its entirety. In other embodiments, at least one of the two suture anchors may be an Arthrex Biocorkscrew™, disclosed in U.S. Patent Application Publication No. 2004/0106950, the disclosure of which is hereby incorporated by reference in its entirety, having an eyelet and loaded with a single or double strands of sutures.

[0031] In an exemplary embodiment, suture anchors 30 have a flexible elongated member 40 (for example, suture 40) preferably attached to a proximal end 42, as illustrated in FIG. 4. One strand of suture 40 from each anchor 30 (preferably opposite colors) is removed. Using a suture retriever instrument 44, one of the four remaining sutures 40 is retrieved through the lateral (or anterolateral) cannula 46 and is passed through the tendon 34 using a suture passer instrument 44. This step is repeated for the three remaining sutures 40 to create a horizontal mattress configuration. When large tears are present, and if desired, all suture strands may be used to obtain additional medial fixation. In this case, the additional strands would be tied and cut.

[0032] Referring now to FIG. 5, the medial row is tied leaving the suture tails 40 uncut. As described below, these suture tails 40 will be draped over the lateral aspect of the tendon 34 and will be held in place with two knotless fixation devices. As also shown in FIGS. 5 and 6, two pilot holes 60 for the knotless fixation devices 62 are formed approximately 5-10 mm distal to the lateral edge of the greater tuberosity using a punch, for example, through the lateral (or anterolateral) cannula 46. In an exemplary embodiment, at least one of the two knotless fixation devices 62 is a fixation device (an Arthrex "PushLock" anchor) as disclosed and described in U.S. Patent Application Publication No. 2004/0093031, the disclosure of which is hereby incorporated by reference in its entirety, or an Arthrex "SwiveLock" anchor as described below with reference to FIGS. 11-13.

[0033] As illustrated in FIG. 6, one suture strand 40 from each suture anchor 30 is retrieved through the lateral (or anterolateral) cannula 46. Both suture strands 40 are then threaded through an eyelet 64 of the knotless fixation device 62 (for example, through the eyelet of the PushLock anchor or of the SwiveLock anchor) on the distal end 66 of the driver 68.

[0034] Subsequently, and as shown in FIG. 7, the distal tip 66 of the knotless fixation device 62 is brought to the edge of the pilot hole 60 while holding onto the suture tails 40. This will reduce the tendon 34 to its desired position on the footprint. Also, the knot stack from the medial suture anchors 30 is forced to lie flat against the tendon 34 minimizing potential impingement issues from the suture 40.

[0035] The driver 68 is then completely advanced into the pilot hole 60 beyond the first laser line, until the anchor body 63 contacts the bone and the tissue tension is evaluated (FIG. 8). If it is determined that the tension is not adequate, the driver 68 can be backed out and the tension readjusted. Alternatively, additional tension may be applied, while leaving the driver 68 in place, by pulling on each suture strand 40 independently. A mallet 80 may be employed to

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impact the anchor body **63** into the pilot hole **60** until the second laser line is flush with the humerus.

[0036] Referring now to FIG. 9, the driver **68** is turned counterclockwise to disengage the eyelet (within pilot hole **60**) from the driver shaft. The sutures **40** are then cut flush using a suture cutter (not shown). The steps described above with reference to FIGS. 6 through 9 are subsequently repeated for the second knotless fixation device **62** (for example, a second PushLock anchor) to obtain the criss-cross suturing arrangement **82** of FIG. 10 having double rows of fixation devices. The criss-cross suturing arrangement **82**, together with the two suture anchors **30** combined with knotless lateral fixation using the two knotless fixation devices **62** form exemplary repair system **100** (FIG. 10) of the present invention.

[0037] FIGS. 11-13 illustrate exemplary steps of the installation of knotless fixation devices with a swivel anchor implant **200** on driver **68** during a knotless method of attaching tissue to bone according to other embodiments of the present invention. The knotless fixation devices with a swiveling implant **200**, are sold by Arthrex, Inc. under the tradename SwiveLock™, and may be used in lieu of the exemplary PushLock anchors described above with reference to the exemplary knotless rotator cuff repair described in FIGS. 1 through 10. The installation technique is similar to the one described above, except that the lateral fixation is accomplished by threading suture through an implant **200** that swivels on the shaft of the driver, and the implant is secured by an anchor that is screwed (by rotating the shaft of the driver), rather than pushed, over the implant.

[0038] As shown in FIGS. 11(a)-(f), a driver **68** is used to install the knotless fixation devices with a swiveling implant. Driver **68** features a thin cannulated rod **69** passing slidably and rotatably through a cannulated driver assembly. The tip of thin cannulated rod **69** is adapted to accept swivel anchor implant **200** within the cannulation at its tip, preferably via a snap fit. Cannulated rod **69** has a hexagonal outer surface for receiving anchor body (i.e., a screw) **90** having a corresponding cannulation.

[0039] During installation of the knotless anchor having a swiveling implant **200**, the screw **90** is first inserted onto cannulated rod **69** of the driver **68**. As shown in FIGS. 11(a) and (b), screw **90** is loaded onto rod **69** and then fully seated on the shaft end of the driver. FIG. 11(c) illustrates the swivel anchor implant **200**. Traction sutures **71** extending from the proximal end of the swivel anchor implant **200** are threaded through the cannulation of the driver **68** (FIG. 11(c)). Subsequently, the swivel anchor implant **200** is seated on the driver tip and until advanced until it snaps onto place (FIG. 11(d)). A protective tube **94** (FIG. 11(e)) may be placed over the tip of the assembly for shipping purposes. The traction sutures **71** may be looped around the driver handle, as shown in FIGS. 11(f) and (g), and secured in a cleat **98** to prevent the implant **200** from becoming prematurely detached from the driver.

[0040] The knotless fixation devices, whether of the first embodiment (PushLock anchors) or the second embodiment (SwiveLock anchors) advantageously minimize or eliminate the need to tie knots. The use of such anchors also provides secure fixation of the suture construct—the secure suture construct results from the suture being pushed into a pilot hole on the lateral row and held tightly by an anchors.

[0041] The sutures employed in the method of the present invention may be formed of any flexible material. In the preferred embodiment, the sutures forming the construct are made of a high strength suture material, such as Arthrex FiberWire suture, which is described in U.S. Pat. No. 6,716,234 to Grafton et al., the disclosure of which is incorporated by reference in its entirety. In additional embodiments, the suture strands may be FiberWire sutures of alternating colors to maximize repair strength, aid in suture management and provide superior tying characteristics.

[0042] In another preferred embodiment, any flexible elongated member, such as tape, rather than suture, may be employed, to further improve tissue compression, improve fixation in the anchors, and to further hold collagen or bone marrow aspirate better than suture. Preferably, the tape, such as the high strength suture, tape disclosed in U.S. Patent Application Publication No. 2005/0192631, the disclosure of which is incorporated by reference herein, is braided and rectangular-like in cross-section. In another preferred embodiment, an allograft or biological component may be used instead of suture or tape. The allograft or biological component may be comprised of tendon or pericardium, for example, which provides improved tissue repair. In yet additional embodiments, any combination of suture, suture tape, and allograft or biological component may be employed, depending on the characteristics of the specific surgical repair and/or as desired.

[0043] According to additional exemplary embodiments of the present invention, the present invention may be further employed in conjunction with allograft or porous collagen material that may be optionally hydrated with bone marrow aspirate. In the exemplary embodiments illustrated in FIGS. 14 and 15, repair systems **400**, **500** of the present invention comprise, for example, the repair system **100** (described with reference to FIG. 10) and implant material **250**, **350** provided arthroscopically (preferably under the tissue prior or above the tissue) prior to implanting the lateral row of the repair system **100**.

[0044] In exemplary embodiments, implant material **250**, **350** may be porous collagen material (BioSponge™) or tendon allograft (AlloBridge™) that can be readily hydrated or impregnated with a hydrating solution comprising aspirated bone marrow. The hydrating solution may consist essentially of bone marrow, preferably consisting essentially of autogenous bone marrow. Alternatively, the hydrating solution may comprise additional elements, such as various growth factors such as hyaluronic acid, antiseptics and/or antibiotics and medicine materials, in addition to or in lieu of the bone marrow. The BioSponge™ **250** (FIG. 14) or AlloBridge™ **350** (FIG. 15) impregnated or hydrated with bone marrow can act as carrier of bone marrow at the repair site, the bone marrow promoting a biological response to damaged tissue and reinforcing the repair of such damaged tissue. The implanted material **250**, **350** may be provided at various locations of the repair site (for example, above the tissue, under the tissue, or extending from the tissue) depending upon the characteristics of the repair site and of the damaged tissue.

[0045] During the surgical repair, the bone marrow aspirate provides a cell suspension that can be readily processed intraoperatively for immediate implantation. According to

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exemplary embodiments, the bone marrow aspirate may be withdrawn from the iliac crest or may be aspirated from the femur and humerus. Once the bone marrow aspirate is aspirated (with a syringe, for example) from an aspirate region such as the humeral head, the BioSponge™ or AlloBridge™ is hydrated with the bone marrow and then the hydrated BioSponge™ or AlloBridge™ is provided arthroscopically (for example, under the tissue) prior to implanting the lateral row implants of system 100. Alternatively, or additionally, bone marrow aspirate may be injected directly or localized to a repair site, to facilitate healing.

[0046] The bodies of the fixation devices of the present invention may be preferably formed of a translucent or transparent polymer material, and are preferably made of bioabsorbable materials such as polyglycolic or polylactic acid polymers.

[0047] Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. Accordingly, it is not intended that the present invention be limited to the illustrated embodiments, but only by the appended claims.

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A knotless method of attaching soft tissue to bone, comprising:

providing a first medial row constructed with a first plurality of fixation devices, wherein the at least one of the first plurality of fixation devices is an anchor;

providing a second lateral row constructed with a second plurality of fixation devices, wherein the at least one of the second plurality of fixation devices is a knotless fixation device;

passing a flexible member through the soft tissue and over a lateral portion of the soft tissue, the flexible member being attached at one end to the anchor and secured at an opposite end in a hole in bone by the knotless fixation device without tying a knot.

2. The method of claim 1, further comprising the formation of a structure of multiple passes of said flexible member over the soft tissue, wherein the structure is held in place by the fixation devices in the first and second medial rows.

3. The method of claim 2, wherein the flexible member of the structure is comprised of suture.

4. The method of claim 2, wherein the flexible member of the structure is comprised of tape.

5. The method of claim 2, wherein the flexible member of the structure is comprised of an allograft or biological component.

6. The method of claim 2, further comprising the step of providing an implant material adjacent to the structure of multiple passes.

7. The method of claim 6, wherein the step of providing an implant material further comprises:

providing aspirate bone marrow;

providing a material to be implanted in the vicinity of a repair site defined by at least the structure of multiple passes;

hydrating the material with aspirate bone marrow to form the implant material; and

securing the implant material at the repair site.

8. The method of claim 6, wherein the implant material is selected from the group consisting of collagen, allograft and bone marrow.

9. The method of claim 8, wherein the implant material is porous collagen impregnated with autogenous bone marrow.

10. The method of claim 8, wherein the implant material is tendon allograft impregnated with autogenous bone marrow.

11. A knotless method of attaching soft tissue to bone, comprising:

inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of an elongated flexible member secured to the first anchor prior to insertion;

inserting the first anchor into the bone;

passing the length of the elongated flexible member over the soft tissue; and

securing, after said step of passing, the length of the elongated flexible member to a second anchor.

12. The method of claim 11, wherein said step of securing the length of the elongated flexible member comprises, in order:

inserting the second anchor with the length of the elongated flexible member coupled thereto into the bone;

tensoring the length of suture; and

securing the length of the elongated flexible member to the second anchor.

13. The method of claim 12, wherein the step of inserting the second anchor comprises inserting the anchor directly into the bone without the anchor passing through the soft tissue.

14. The method of claim 11, wherein the step of securing the elongated flexible member to the second anchor is performed without tying any knots.

15. The method of claim 11, wherein the second anchor is a press-in suture anchor.

16. The method of claim 11, wherein the second anchor is a suture anchor with a swivel implant.

17. A knotless method of attaching soft tissue to bone, the method comprising:

inserting a first, second, and third anchor into the bone;

fixedly securing a first length of a flexible elongated member over the soft tissue to the first and second anchors; and

fixedly securing a second length of the flexible elongated member over the soft tissue to the first and third anchors.

18. The method of claim 17, wherein the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue.

19. The method of claim 17, wherein the first and second lengths of the elongated flexible member are fixedly secured to the first anchor prior to insertion into the bone.

20. A knotless method of attaching soft tissue to bone, comprising:

inserting a first anchor with a length of an elongated flexible member attached thereto through the soft tissue;

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inserting the first anchor into the bone;

inserting a second anchor with no suture attached thereto into bone;

passing the length of the elongated flexible member over the soft tissue; and

fixedly securing the length of the elongated flexible member to the inserted second anchor.

21. The method of claim 20, further comprising, after inserting the first anchor into the bone, fixedly securing the attached length of the elongated flexible member to the first anchor.

22. The method of claim 20, wherein the step of fixedly securing the attached length of the elongated flexible member to the first anchor is performed without tying any knots.

23. The method of claim 20, further comprising the step of tensioning the elongated flexible member prior to the step of fixedly securing the elongated flexible member to the first anchor.

24. The method of claim 23, wherein the step of tensioning the flexible elongated member comprises grasping the length of the flexible elongated member and pulling.

25. A method of attaching soft tissue to bone, comprising: providing a first medial row constructed with a first plurality of fixation devices, wherein the at least one of the first plurality of fixation devices is an anchor;

providing a second lateral row constructed with a second plurality of fixation devices, wherein the at least one of the second plurality of fixation devices is a knotless fixation device;

providing an implant material adjacent the first medial row and adjacent the soft tissue;

providing a flexible member attached to the first medial row; and

passing the flexible member through the soft tissue and over a lateral portion of the soft tissue to form a structure of multiple passes of said flexible member over the soft tissue.

26. The method of claim 25, wherein the implant material is porous collagen impregnated with autogenous bone marrow.

27. The method of claim 25, wherein the implant material is tendon allograft impregnated with autogenous bone marrow.

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